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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,192	07/02/2003	**Ranajit Pal**	00711CIP	4134

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EXAMINER	
PENG, BO	
ART UNIT	**PAPER NUMBER**
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/612,192	PAL ET AL.	
	Examiner	Art Unit	
	BO PENG	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1- 21* is/are pending in the application.

4a) Of the above claim(s) *8-14 and 16-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,15 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to the reply filed April 23, 2008. Claims 1-21 are pending. Claims 8-14 and 16-20 have been withdrawn from consideration as nonelected inventions. Claims 1-7, 15 and 21 are considered in this Office action.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. **(Prior rejection-withdrawn)** The rejection of Claim 3 under 35 U.S.C. 112, second paragraph for lacking antecedent basis for "cryptic epitopes" in Claim 1, **is withdrawn** in view of Applicant's argument.

Claim Rejections - 35 USC § 112, first paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. **(Prior rejection- maintained)** The rejection of Claims 1-7, 15 and 21 under 35 U.S.C. §112, first paragraph, as failing to comply with the **written description** requirement **is maintained**, for the reason of record.

In response to Applicant's arguments:

Applicant provides following argument in Remarks, pp. 10-11:

Firstly, not all of the claims are directed to a vaccine. Accordingly, this assertion by the examiner alone is insufficient to support the above rejection of all of claims 1-7, 15, and Secondly, as discussed above, claim 15 is directed only to a "vaccine", and not specifically and "HIV vaccine". Thus, as stated above, the application need not enable an "HIV" vaccine. Also as stated above, vaccines, in general, are enabled in the art. The specification has simply added to that enablement, by describing the components in claim one which may be included in a vaccine. It is sufficient that the Application has enabled simply a vaccine with the components of Claim 15, as this is what is claimed. Therefore, Applicants respectfully assert that Examiner's rejection of claims 1-7, 15, and 21 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, is improper and that claims 1-7 are in allowable form.

6. This argument is irrelevant to the basis for the lacking of written description rejection presented in the previous Office actions. The previous Office actions indicated that Claim 1 lacks an adequate written description because the specification has not defined what is "the conformation of any fragment of CD4". A fragment of CD4 could be any pieces of CD4 molecule from as small as two amino acid residues to as big as whole CD4 molecule Such CD4 fragments have totally different conformations. Under these conditions, the specification has not adequately described what specific conformation the alleged "equivalent of a fragment of CD4" mimics, so that it "reveals cryptic epitopes" (Claim 3). Since "the conformation of any fragment of CD4" and "cryptic epitopes" is not conventional in the art or known to one of ordinary skill in the art, one of ordinary skill in the art cannot envision what is "any molecule that mimics the confirmation of any fragment of CD4" and reveals "cryptic epitopes" without an adequate description by the specification. Therefore, the rejection is maintained.

7. (**Prior rejection- maintained**) The rejection of Claims 1-7, 15 and 21 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the

specification commensurate in scope with these claims, **is maintained** for the reason of record.

In response to Applicant's arguments:

8. Applicant asserts that regarding the phrase "the conformation of any fragment of CD4", the only words the Examiner can possibly be asserting that are not conventional are "conformation" and "fragment of CD4". Then Applicant goes on explain "conformation" using the definition in Wikipedia submitted as Appendix B and C.

9. This argument is not relevant to the rejection. While Appendix B and C describe conformation of a protein, they are not descriptive of the specific structural limitation of "**the conformation of any fragment of CD4"** in the claims. Because of the lack of written description of the claimed "an equivalent" in the specification as discussed above, one of ordinary skill in the art would not know how to make alleged gp120-CD4 equivalents.

10. **(Prior rejection-maintained)** The rejection of Claim 15 under 35 U.S.C. 112, first paragraph, for failing to comply with the enablement requirement **is maintained** for the reason of record.

In response to Applicant's arguments:

11. First, Applicant presents the same argument words-by-words as in the previous reply filed on August 14, 2007, see e.g. Remarks, p. 3-Para 1, p. 6. Applicant asserts that the instant specification has set forth how to use the invention to assist in the creation of a vaccine.

12. This argument has been found not persuasive for the reasons discussed in Paragraphs 7 and 8 of the Office action dated January 23, 2008; also see the Office actions dated May 15, 2007, and November 20, 2006.

13. In addition, Applicant asserts that Examiner seems to be improperly amending the language of Claim 15 to read "A vaccine for HIV comprising", then proceed to discuss the challenges in HIV vaccine development. Applicant asserts that Claim 15 only states "A vaccine comprising...", not "A vaccine for HIV comprising ....". Accordingly, the Application need not enable "A vaccine for HIV comprising", and the Application has enabled a vaccine with the components of Claim 15, as is claimed.

14. This argument is not convincing. MPEP 904.01 recites: "During patent examination, the claims are given the broadest reasonable interpretation consistent with the specification" (Emphasis added). Specifically, the alleged vaccine of Claim 15 reads on a vaccine for HIV because it is consistent with the instant application. The DESCRIPTION OF THE INVENTION of the present application recites as below:

> DESCRIPTION OF THE INVENTION
> We have discovered that a gp120-CD4 covalently bonded complex presents a specific subset of cryptic epitopes on gp120 and/or CD4 not present on the uncomplexed molecules. This complex elicits neutralizing antibodies with novel specificities and is thus useful in vaccines and immunotherapy against HIV infection. We have also discovered that **complexes including gp120 covalently bonded to a fragment of CD4 elicit neutralizing antibodies and are therefore useful in vaccines and immunotherapy against HIV infection.** In addition, these complexes or antibodies thereto can be used in immunological tests for HIV infection (Specification, Para 2, p. 1).

Since the application clearly describes the instant invention is intended use for vaccines and immunotherapy against HIV infection, "A vaccine" of Claim 15 properly read on a vaccine for HIV, not any vaccine. Therefore, the Application need enable the claimed

vaccine for HIV. The previous Office actions have provided detailed discussion why the instant specification does not enable a vaccine for HIV. Therefore, Applicant's argument is not convincing, and rejection is maintained.

Claim Rejections – 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. (Prior **rejection-withdrawn)** Claims 1-3, 5, 7, 15 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Hart T. *et al* (Proc Natl Acad Sci U S A. 1991 Mar 15;88(6):2189-93), **is withdrawn** in view of Applicant's argument.

Double Patenting

17. **(Prior rejection-maintained)** The rejection of Claims 1-7, 15 and 21 on the ground of nonstatutory obviousness-type double patenting over Claim 1 of US 5,843,454, and Claim1 of US 5,518,723 **is maintained** for the reasons of record.

18. Applicant acknowledges the rejection and does not wish to prematurely respond.

Remarks

19. No claim is allowed. **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, Ph. D. can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Bo Peng/
Patent Examiner
August 6, 2008

/Zachariah Lucas/
Primary Examiner, Art Unit 1648